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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,997	08/29/2001	Qinwei Shi	1112-1-052CON	9957

23565 7590 02/05/2008

KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/941,997	SHI ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-15* is/are pending in the application.

4a) Of the above claim(s) *4-8 and 10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2007 has been entered.

Amendment Entry

2. The amendment filed September 14, 2007 has been entered. Claims 1 and 9 have been amended. Claims 2 and 16 have been cancelled. Claims 4-8 and 10-15 have been withdrawn. Claims 1, 3 and 9 are under consideration in this office action.

Response to Arguments

3. Applicant's arguments filed September 14, 2007 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The new matter rejection of claim 9 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.

Claim 9 is drawn to an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino acid residues 20 to 30, and a C-terminus of the fragment is amino acid residues 95 to 115 of native human cardiac troponin I.

The rejection is on the grounds that neither the specification nor originally presented claim provides support for isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino acid residues 20 to 30 and a C-terminus of the fragment is amino acid residues 95 to 115 of native human cardiac troponin I.

Applicants urge that the change in the claim overcomes the rejection. However, applicant failed to point to support in the specification for an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino acid residues 20 to 30 and a C-terminus of the fragment is amino acid residues 95 to 115 of native human cardiac troponin I. Paragraphs 10-12 discuss the N-terminal portion of native human cardiac troponin I consisting of about 95 to about 115 amino acids, and extending from about amino acid 20-30 to about amino acid 95-115 of native cardiac troponin I. There is no discussion of the N-terminus of the fragment is amino acid residues 20 to 30 and a C-terminus of the fragment is amino acid residues 95 to 115 of native human cardiac troponin I. There is no disclosure C-

terminus fragments at all. Applicants have not pointed to any support within the specification.

Paragraph 22 states stable human cardiac troponin I fragments comprising an N-terminal sequence of about 95 to 115 amino acids. Degradation cleaves 20-30 amino acids from the N-terminus, producing a fragment of about 65 to 95 amino acids in length. The term polypeptide, marker or fragment used in the singular refers to an amino acid sequence corresponding to the N-terminal portion of human cardiac troponin I extending from the native N-terminus to about 95 to about 115 amino acids and that with the 20-30 N-terminal amino acids absent. There is no disclosure of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to 30. There is no disclosure of a C-terminus fragment. Neither the specification nor originally presented claims provides support for isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino acid residues 20 to 30 and a C-terminus of the fragment is amino acid residues 95 to about 115 of native human cardiac troponin I.

Applicant failed to specifically point to the identity or provide structural characteristics of an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino acid residues 20 to 30 and a C-terminus of the fragment is amino acid residues 95 to 115 of native human cardiac troponin I. There appears to be no teaching of that isolated polypeptide within the instant specification or originally filed claims for support of the amendment; thus it appears that the entire specification appears to fail to recite support for the newly

recited isolated polypeptide. Applicants must specifically point to page and line number support for the identity an isolated polypeptide isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino acid residues 20 to about 30 and a C-terminus of the fragment is amino acid residues 95 to 115 of native human cardiac troponin I. Therefore, contrary to applicants' assertion, the claim incorporates new matter and the rejected is maintained.

New Grounds Of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 is drawn to an isolated polypeptide consisting of an N-terminus fragment of human cardiac troponin with at least 95 amino acids of SEQ ID NO:2 and a length of 115 amino acids. Claim 9 is drawn to an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino acid residues

20 to 30, and a C-terminus of the fragment is amino acid residues 95 to 115 of native human cardiac troponin I.

No information, beyond the characterization of a polypeptide having at least 95 amino acid of SEQ 1D NO: 2 have been provided, which would indicate that applicants had possession of the claimed genus of polypeptides having a length of 115 amino acids. The specification does not contain any disclosure of the structure of all the mutants or variants of any polypeptide polypeptide consisting of an N-terminus fragment of human cardiac troponin with at least 95 amino acids of SEQ ID NO:2 and a length of 115 amino acids or an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino acid residues 20 to 30, and a C-terminus of the fragment is amino acid residues 95 to 115 of native human cardiac troponin I within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including variants, which can have wide variety of structures. The specification discloses the structure of only a single representative species of the claimed genus i.e. SEQ ID NO: 2, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The nucleic

acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

The specification fails to provide guidance on the structure of the polypeptide. Structural features that could distinguish molecules in the genus from others in the class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. The specification and claims lack sufficient written description of the generically claimed polypeptides. In the present instance, the claim is drawn to a fragment of troponin I with at least 95 to 115 amino acids wherein SEQ ID NO:2 and a length of 115 amino acids. The specification fails to describe a polypeptide consisting of an N-terminal fragment, wherein the fragment is longer than SEQ ID NO:2. Claim 1 recites the broad limitation of a length of 115 amino acids. The claim also recites the fragment being at least 95 amino acids, and the claim also recites SEQ ID NO:2 which have 99 amino acids. There is no description of a polypeptide having at least 95 amino acids of SEQ ID NO:2 99 amino acids are within the fragment. There is no description of what the additional unidentified amino acids are that will be included to have a length of 115 amino acids.

The written description in this case only sets forth specific sequence (SEQ ID NO:2), therefore the written description is not commensurate in scope with the claims drawn to fragments. Neither the specification nor the claims teach how to define fragments. Neither the claims nor the specification teach how to obtain such fragments.

There is no guidance as to what the fragments are; or what fragments can or cannot be used in the polypeptide being claimed. The specification does not include structural examples fragments. Thus, the resulting fragment could result in a complex not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of the claimed polypeptides. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites an N-terminus fragment being amino acid

residues 20 to 30. It is unclear what residues 20 to 30 are, are amino acid residues 20 to 30 the residues from the wild type sequences or some other sequence. Therefore clarification is required to overcome the rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 28, 2008

MARK NAVARRO
PRIMARY EXAMINER